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§21–216.

(a) For purposes of this subtitle, a drug or device is adulterated if the standards in this section apply.

(b) A drug or device is adulterated if:

(1) Any part of it is a filthy, putrid, or decomposed substance; or

(2) It was produced, prepared, packed, or held under unsanitary conditions that reasonably would be expected to have:

(i) Contaminated it with filth; or

(ii) Caused it to be injurious to health.

(c) In addition to the grounds specified in subsection (b) of this section, a drug is adulterated if:

(1) Any part of its container is composed of any poisonous or otherwise deleterious substance that reasonably would be expected to have caused the drug to be injurious to health;

(2) For purposes of coloring only, it is or it contains a color additive, the particular use of which has not been found safe as provided under § 21–239 of this subtitle;

(3) The mixing or packing of any substance with the drug has reduced the quality or strength of the drug;

(4) Any substance has been substituted for any part of the drug;

(5) The methods, facilities, or controls used in the manufacture, processing, packing, or holding of the drug do not conform to, or are not administered in conformity to, good practice to assure that the drug:

(i) Meets the requirements of this subtitle as to safety; and

(ii) Has the identity, strength, quality, and purity that it purports to have;

(6) It is purported to be a drug the name of which is recognized in an official compendium and:

(i) The strength of the drug differs from, or the quality or purity of the drug falls below, the standard set in the official compendium; and

(ii) The difference in strength, quality, or purity is not stated plainly on its label; or

(7) Although not purported to be a drug recognized in an official compendium, the strength of the drug differs from, or the quality or purity of the drug falls below that which the drug purports to possess.

(d) (1) For purposes of administering subsection (c)(6) of this section, any determination as to whether the strength of a drug differs from or as to whether its quality or purity falls below the standard set in an official compendium shall be made in accordance with the tests or methods of assay set forth in the official compendium, or, in the absence of or inadequacy of those tests or methods of assay, those provided under the federal act.

(2) (i) Except as provided in subparagraph (ii) of this paragraph, if a drug is recognized in both the United States Pharmacopoeia and National Formulary and in the Homeopathic Pharmacopoeia of the United States, it is subject to the requirements of the United States Pharmacopoeia and National Formulary.

(ii) If the drug is labeled and offered for sale as a homeopathic drug, it is subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia and National Formulary.

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